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Critical Business: Controlling the Flow

Flow-control specialist Vernay Labs boosting its medical profile in U.S., Europe

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July 2021

Flow-control valves in medical devices keep patients alive. Pure and simple. Whether it involves dosing intravenous drugs, moving blood or other fluids, or performing key functions in surgical or diagnostic equipment, these precision components must conform to rigorous regulatory mandates and perform without fail.

With headquarters in Atlanta, GA, Vernay Labs has long supplied a vast array of engineered elastomeric parts to the medical industry. We design and custom manufacture critical flow-control valves for leading OEMs and medical device manufacturers worldwide for use in a vast array of medical and pharmaceutical applications.

Never has Vernay seen a greater need for its medical products than in the past year, when the COVID-19 pandemic spurred unprecedented demand for life-saving devices. Already a key supplier to Ventec Life Systems, Vernay stepped up its game — and production capacity — when Ventec very publicly partnered with General Motors to urgently increase output of its critical-care ventilators. Within the first couple of weeks of the pandemic, Vernay realized that they supplied the majority of ventilator manufacturers across the world. This happened over and over again as Vernay components are used not only in “visible” medical devices, they are also used in the industrial mixing of chemicals for sanitizers and disinfectants. With Vernay manufacturing facilities shut down due to lockdowns in China and Italy; the Griffin, GA plant successfully managed double digit

volume increases with communication and collaboration between all of the Global Vernay teams (production, maintenance, sales, procurement, logistics and customer service).

Vernay not only delivers parts, but delivers quality and functionality and to make a difference in people's lives. Vernay is positioned to serve customers in all regions of the world with engineering, testing, and manufacturing capabilities in the U.S., Italy, the Netherlands, and China. In addition, it has sales and customer service offices in Germany, Japan, and Singapore.

Clean Room Investments

To further bolster our ability to serve medical device market demands, Vernay is investing in both the United States and Europe to add more than 15,000 square feet of clean room space.

The company recently earned ISO Class 8 clean-room certification for the assembly area at its Griffin, Ga., plant. Overseeing this effort is Vernay Quality Systems Manager Christina Ward, a 21-year veteran in medical manufacturing.

“The need for precision engineering in medical components is obvious. Vernay clearly meets those standards and is now taking a step forward by certifying an adjacent manufacturing space in the Griffin plant also as an ISO class 8 clean-room. This is a much bigger challenge, given that the area houses more than 18 molding presses and 30 finishing/assembly stations,” Ward explained. A major part of the initiative involves educating and training employees who work in the medical area about all the necessary protocols, and Ward is leading these efforts.

“The pandemic certainly created its own set of challenges. But gaining the desired additional clean-room certification will be very good for Vernay” Ward notes “It will both open the door to new customers, and allow us to expand our offerings to existing customers.”

Additionally, Vernay is building a new clean room at its facility in Asti, Italy, due to be completed by year’s end. Vernay Italia is expanding its entire 43,000-square-foot facility in Asti, southwest of Milan. The site currently has a soft-wall, ISO 8 clean room used for the washing and packaging of products and is in the midst of expanding the area, according to Vanna Villata, Managing Director of Vernay Italia and a 35-year veteran of the company. The expansion will address increased customer demands and allow for the additional manufacturing and assembly of products in the development pipeline.

“We do custom elastomeric molding, overmolding and assemblies of rubber, plastic and metal parts,” Villata said. “We don’t just supply a rubber part — we design, develop and manufacture fully functioning and fully tested assemblies and connectors for complex flow control needs.” The 125-person Asti plant produces more than 300 million parts for applications in the global fluid-control marketplace annually and is posed to grow exponentially, serving increased medical demands throughout Europe and Asia.

Dealing with COVID-19 in Italy

Like many firms in Northern Italy, Vernay Italia shut down for more than a month in spring 2020 due to the region's Covid-19 coronavirus outbreak. "The authorities did not initially recognize how important our products were to the medical supply chain," said Mauro Gertosio, Technical and Quality Director at Vernay Italia. As a result, he put together a team focused on that sector and together they took on the task of becoming ISO-13485 certified. The site had already been adhering to those ISO guidelines, so in just a few weeks — in the midst of the pandemic — they gained the ISO certification.

"We worked diligently with the Italian government to be designated as an 'essential business' and we were able to reopen the plant in May 2020," Gertosio explained, "doing so meant that we could resume supplying parts for ventilators, blood pumps, oxygenators, and disposable surgical supplies. This episode also helped us to accelerate our plan to expand our facility and gain an ISO Class 7 clean room certification. This will ensure that we will always be able to stay open and reliably supply our customers."

Vernay's Medical Horizon

Following a streamlined, integrated methodology from concept to launch, Vernay takes responsibility for designing the optimal medical component for each customer's application. Over 85% of all components produced by Vernay are custom parts designed specifically for a customer's unique need. Devices relying on Vernay components include those used in cancer tissue diagnosis, bio-reactors, microfluidics, minimally invasive surgeries, pediatric respiratory inhalers, anesthesia delivery, one-way valves and septums for bag systems, dialysis, negative wound pressure therapies and more. These are a few of the engineered solutions Vernay produces for critical medical applications using a variety of molding and processing techniques –transfer, compression, injection, flashless and liquid injection (LIM) including overmolding, bonding and welding and utilizing inline leak and flow testing and camera systems.

Over the years, the company developed more than 33,000 elastomeric materials and compound formulations tailored precisely to each end use. This sort of expertise coupled with proprietary molding software simulation (linear and non-linear) is vital given

that elastomers behave differently from plastics and knowing and understanding the flow is the key. In many applications, the flow control determines the success or failure of the device – this is why Vernay's knowledge and expertise is so important and for custom medical and pharmaceutical applications Vernay's design and development engineers are vitally needed.

With the ISO 8 Cleanroom certification in the US and the expansion and ISO 7 Cleanroom certification in Europe, Vernay is ready and able to take on additional medical business and solve problems that medical device manufacturing and pharma companies have.

Tara Bryce – Global Medical Business Unit Manager

Tara Bryce has been in the medical device / pharmaceutical primary packing industry for over 10 years working with startups, large pharma and global medical device manufacturers as a supplier and CMO in business development, sales and marketing.